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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,710	07/10/2000	DAVID J. COLE	33083-PCTUS	7491

21003 7590 07/01/2003

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NEW YORK, NY 10112

EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

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DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/508,710

Applicant(s)

COLE ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2003 and 16 April 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2-4, 8-15, 20-23, 25-27, 29-32, 43, 68-73, 75-78 and 80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3, 22, 27, 30-32, 43, 68-73, 75, 76, 78 and 80 is/are rejected.
- 7) ☒ Claim(s) 2, 4, 8-15, 20, 21, 23, 25, 26, 29 and 77 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **STATUS OF THE APPLICATION**

1. This Office action is in response to Applicant's Amendment and Remarks filed 21 January 2003 and Applicant's response filed 16 April 2003.
2. The corrected Marked Up Version Of Amended Claims filed 16 April 2003 has been entered into the file.
3. Claims 2-4, 8-15, 20-23, 25-27, 29-32, 45, 68-73, 75-78 and 80 are pending.
4. The objection to the specification as directed to the abstract of the disclosure submitted 31 May 2002 is now moot, the abstract submitted 21 January 2003 is in compliance with the rules.
5. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's amendments and/or arguments filed 21 January 2003.
6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Priority***

7. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 120 and 365 as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). If the application claims the benefit of an international application, the first sentence of the specification must include an indication of whether the international application was published under PCT Article 21(2) in English (regardless of whether benefit of such application is claimed in the

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application data sheet). Applicant is required to insert into the first line of the specification the following statement: -- This application is the National Stage of International Application No. PCT/GB98/02802, filed 16 September 1998, published in English. --.

### ***Claim Objections***

8. Claim 2 is objected to under 37 CFR § 1.75(c) as being in improper form because a multiple dependent claim must refer to other claims in the alternative only. See MPEP § 608.01(n). Appropriate correction is required.

9. Claims 4 and 20 are objected to because of the following informalities:

At claim 4, line 2, the phrase "is coding sequence of" lacks an article of language. It is recommended that the phrase read -- comprises --.

At claim 20, "(a)" should be changed to -- (b) --, because this is a distinct, optional step.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

10. Claims 3, 22, 27, 30-32, 43 and 78 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claim 3, line 2, the phrase "the coding sequence" lacks proper antecedent basis within the claim.

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Claim 22 is indefinite because the method of claim 21 does not produce a transgenic plant at step (a). Also, claim 22 can depend from claim 21 only to the extent that it modifies or adds to the method steps of claim 21.

At claim 27, lines 2-3, the phrase “, first-generation, plant, plant seed or progeny plant” lack proper antecedent basis in claim 25, inserting -- produced from the transgenic plant cell -- after said phrase would obviate this issue. In addition at line 2, the phrase “a transgenic plant cell” should read -- the transgenic plant cell -- in referring to claim 25.

At claim 30, line 2 the phrase “step (b)” is indefinite because claim 29 does not have a step (b) and is not directed to a method. Claims 31 and 32 are also indefinite because they do not obviate the indefiniteness of claim 30.

At claim 43, line 2, the phrase “transgenic first-generation plant or transgenic progeny plant” lacks proper antecedent basis in claim 25, inserting -- produced from the transgenic plant cell -- after said phrase would obviate this rejection.

Claim 78 is indefinite because it is unclear if the plant seed or progeny plant is transgenic. Claim 78 is also indefinite because it is dependent upon claim 22 and does not obviate the indefiniteness of claim 22.

11. Claims 68-73, 75, 76 and 80 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is

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repeated for the reason of record as set forth in the last Office action mailed 22 October 2002. Applicant's arguments filed 21 January 2003 have been fully considered but they are not persuasive.

Applicant argues that the specification teaches homologues of SEQ ID NO: 1 and teaches GST sequences with modified nucleotides and/or backbones (page 7 of the Remarks). Applicant argues that the specification teaches ways of identifying allelic variants of GST sequences related to SEQ ID NO: 1, the properties of an allelic variant, GST sequences with optimized codon usage and/or engineered restriction sites and how to produce conservative substitutions. Applicant argues that the specification teaches 8 additional polynucleotide sequences, which are species of claim 1 and 2, and provides an adequate written description commensurate with the scope of claims 1 and 2 (page 8, 1<sup>st</sup> paragraph of the Remarks). As directed to the instant rejected claims, the Examiner maintains that Applicant has failed to adequately describe the claimed isolated polynucleotides having 70%-99% sequence identity to SEQ ID NO: 1, 95% or 99% identical to at least about 100 contiguous nucleotide of SEQ ID NO: 1, or that encodes a GST subunit having a sequence of SEQ ID NO: 2 modified by up to about 30 conservative amino acid substitutions as broadly claimed. It is unclear that Applicant has adequately described the claimed genus(es) of isolated polynucleotide(s). Applicant only describes generally modification of polynucleotides to comprise conserved substitutions or that encode conservative amino acid substitutions.

See *Amgen inc. v Chagai Pharmaceutical co.*, 18 USPQ 2d 1016 (Fed. Cir. 1991), which teaches that the conception of a chemical compound requires the inventor

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to be able to define the compound so as to distinguish it from other materials, and to describe how to obtain it rather than simply defining it solely by its principle biological property; thus, when an inventor of a gene, which is a chemical compound albeit a complex one, is unable to envision detailed constitution of the gene so as to distinguish it from other materials, as well as a method of obtaining it, the conception is not achieved until a reduction to practice has occurred, and until after the gene has been isolated. In the instant case, Applicant does not adequately describe the genus of isolated polynucleotides within the claimed percent identity to SEQ ID NO: 1, or that encodes a polypeptide having the sequence of SEQ ID NO: 2 modified by up to about 30 conservative amino acid substitutions.

Applicant's arguments on page 8, 3<sup>rd</sup> paragraph to page 9 of the Remarks as directed to claims 68-76 and 79-80 allegedly being indefinite are irrelevant to the instant rejection as directed to adequate written description.

12. Claims 68-73, 75, 76 and 80 remain rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide that encodes the amino acid sequence of SEQ ID NO: 2, does not reasonably provide enablement for any isolated polynucleotide that is 70%-99% identical to SEQ ID NO: 1 or that encodes a GST having the sequence of SEQ ID NO: 2 modified by up to about 30 conservative amino acid substitutions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reason of record as set forth in the last Office

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action mailed 22 October 2002. Applicant's response filed 21 January 2003, page 9, 2<sup>nd</sup> paragraph to page 10 of the Remarks does not put forth any arguments as directed to this rejection. The Examiner maintains that the instant claims are not fully enabled for the claimed isolated polynucleotides. It is unclear from the instant specification that Applicant has taught the claimed genus of polynucleotides, even given the teaching of multiple polynucleotides encoding wheat GST coding sequences.

See *Amgen inc. v Chagai Pharmaceutical co.*, 18 USPQ 2d 1016 (Fed. Cir. 1991), which teaches that it is necessary that the inventor provide a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of the claims, for DNA sequence that means disclosing how to make and use enough sequences to justify grant of the claims sought.

### **Conclusion**

13. This action is non-final.
14. The claims are free of the prior art.
15. Claims 3, 22, 27, 30-32, 43, 68-73, 75, 76, 78 and 80 remain/are rejected.
16. Claims 2, 4, 8-15, 20, 21, 23, 25, 26, 29 and 77 are objected to.



17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "Amy Nelson", with a stylized, flowing script.

David H. Kruse, Ph.D.  
25 June 2003

**AMY J. NELSON, PH.D**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**